

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

APOTEX, INC.,

Plaintiff,

v.

**DAIICHI SANKYO, INC. and
DAIICHI SANKYO CO., LTD.**

Defendants.

Case No.: 12-CV-09295

**Judge Sharon Johnson Coleman
Magistrate Judge Mary M. Rowland**

**MEMORANDUM IN SUPPORT OF DEFENDANTS’
MOTION TO DISMISS PLAINTIFF’S AMENDED COMPLAINT**

Pursuant to Federal Rule of Civil Procedure 12(b)(1), Defendants Daiichi Sankyo, Inc. and Daiichi Sankyo Co., Ltd. (collectively “Daiichi Sankyo”) submit this memorandum in support of their motion to dismiss Plaintiff Apotex, Inc.’s (“Apotex”) amended complaint.

PRELIMINARY STATEMENT

No real dispute exists between the parties. Apotex frames this case as a request for declaratory judgment of non-infringement of United States Patent No. 6,878,703 owned by Daiichi Sankyo. But, that patent does not even exist, because it was disclaimed by Daiichi Sankyo in 2006. Daiichi Sankyo also told Apotex that it will *never* sue Apotex or anyone else on that non-existent patent and indeed it cannot. There is no, and cannot be, any real and justiciable dispute about infringement of a disclaimed and non-existent patent.

Apotex’s complaint tries to argue that the FDA’s regulatory system for generic drug approvals codified by the Hatch-Waxman Act somehow conveys jurisdiction. According to Apotex, this patent is the roadblock to Apotex’s market entry under the Act. But, this patent

does not and cannot hinder Apotex's market entry; instead, Apotex is being excluded from the market by a different Daiichi Sankyo patent to which Apotex has acquiesced, and by regulatory exclusivity to which non-party Mylan is entitled under the Act. In cases involving indistinguishable facts, the Federal Circuit found no subject matter jurisdiction. Even if this Court had subject matter jurisdiction (which it does not), the Court should, in its discretion, decline to hear this case, because under the Hatch-Waxman Act, Apotex lacks (and may never obtain) the prerequisites for the relief it seeks.

BACKGROUND

A. The Hatch-Waxman Act

To begin, a brief description of the Hatch-Waxman Act is helpful. The Hatch-Waxman Act, a specialized system of laws, governs (among other things) the approval of generic versions of previously approved branded drugs. *See, e.g., Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed. Cir. 2008) (citation omitted). "Branded" (or "innovator") pharmaceutical companies invest decades of research to invent new drugs and perform safety and efficacy testing (including clinical trials) to get such drugs approved by the Food and Drug Administration (FDA). The Hatch-Waxman Act attempts to balance the need to encourage innovation by branded companies with the desire to make generic versions of drugs available.

Before a new drug can be approved by the FDA, the branded company must submit a New Drug Application (NDA) containing the results of chemical testing, animal studies, and clinical trials to prove the safety and efficacy of the drug. These studies take many years and cost millions of dollars to complete. Applicants seeking to market generic versions of previously approved drugs, however, can skip the vast testing required of the branded company and use an expedited approval process called an Abbreviated New Drug Application (ANDA). *See generally* 21 U.S.C. § 355(j). An ANDA applicant can rely on the testing in the branded

company's NDA and merely must prove that its generic product is "bioequivalent" to the NDA product. *See* 21 U.S.C. § 355(j)(2)(A) (listing required contents of ANDA); *see also* 21 C.F.R. § 320.1(e) (defining bioequivalence). The FDA reviews ANDAs for compliance with its regulations. If the ANDA meets the approval requirements, the FDA will grant either "final" approval (and sale can begin immediately), or "tentative" approval (if final approval is barred by some period of regulatory exclusivity).

The Hatch-Waxman Act recognizes that branded companies often have one or more patents that cover their drugs. The branded applicant must identify to the FDA all patents that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists these patents in its *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." For each patent listed in the Orange Book, an ANDA applicant must include a certification stating either that (I) no patent information has been submitted; (II) the patent has expired; (III) approval of the ANDA should be deferred until expiration of the patent; or (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). These options commonly are referred to as Paragraph I, II, III, and IV Certifications.

An ANDA applicant making a Paragraph III Certification acquiesces to the patent and agrees to wait for approval of its ANDA until the patent and attendant exclusivity expires. In contrast, when an ANDA applicant makes a Paragraph IV Certification, the branded company has a cause of action against the ANDA applicant for patent infringement under a provision in the patent statute (35 U.S.C. § 271(e)(2)) added by the Hatch-Waxman Act. If a court

determines that the patent is infringed, the FDA cannot approve the ANDA until the patent expires. *See* 35 U.S.C. § 271(e)(4)(A).

The Hatch-Waxman Act also provides the first generic company to file an ANDA containing a Paragraph IV Certification as to a listed patent (the “first Paragraph IV filer”) with 180 days of generic exclusivity for the listed drug (*i.e.*, the FDA will delay the approval of other ANDAs with Paragraph IV Certifications for the same drug for 180 days). *See* 21 U.S.C. § 355(j)(5)(B)(iv). The first Paragraph IV filer is entitled to this generic exclusivity period even if it loses its litigation with the branded company on some, but not all, of the listed patents.

B. The Drug at Issue Here: Benicar®

Daiichi Sankyo holds the approved NDA for the Benicar® product (olmesartan medoxomil) 5 mg, 20 mg, and 40 mg tablets. In connection with its original NDA filing in 2000, Daiichi Sankyo listed U.S. Patent Nos. 5,616,599 (the “’599 patent”) and 6,878,703 (the “’703 patent”) in the Orange Book. Am. Compl. (D.I. 10), ¶ 24.

In 2006, non-party Mylan Laboratories, Ltd. (“Mylan”) became the first company to file an ANDA for a generic version of Benicar® that included a Paragraph IV certification. *Id.*, ¶ 31. Mylan made a Paragraph IV Certification against both the ’599 patent and the ’703 patent. *Id.* Daiichi Sankyo sued Mylan for infringement of the ’599 patent. *Id.* Daiichi Sankyo did not assert the ’703 patent because, on July 11, 2006, Daiichi Sankyo statutorily disclaimed every claim of the ’703 patent. *See* Am. Compl. (D.I. 10), ¶ 18 and Exh. D; *see also* 35 U.S.C. § 253 (defining statutory disclaimers). Also on July 11, 2006, Daiichi Sankyo requested that the FDA remove the ’703 patent from the Orange Book. *See* Declaration of C. Austin Ginnings, Esq. in Support of Defendant’s Motion to Dismiss Plaintiff’s Amended Complaint (“Ginnings Decl.”), Exh. 1. The Orange Book notes this delisting request. *See id.*, Exh. 2.

Ultimately, the district court found the '599 patent valid and infringed by Mylan, the Federal Circuit affirmed the district court's decision, *see generally Daiichi Sankyo Co. v. Matrix Labs.*, 619 F.3d 1346 (Fed. Cir. 2010), and the Supreme Court denied certiorari, *see Mylan Inc. v. Daiichi Sankyo Co., Ltd.*, 131 S.Ct. 1678 (2011).

Even though Mylan was unsuccessful in its challenge to the '599 patent, it still was the first Paragraph IV filer on both listed patents and is therefore presumptively entitled to 180 days of generic exclusivity after the '599 patent and attendant exclusivities expire in October 2016.¹

C. Apotex's ANDA

Now, years after Mylan filed its ANDA, Apotex submitted an ANDA for a proposed generic Benicar® product. Am. Compl. (D.I. 10), ¶ 26. As part of its ANDA, Apotex included a Paragraph IV Certification with respect to the '703 patent, but *not* the '599 patent. *See id.*, ¶ 27. Apotex has filed a Paragraph III Certification as to the '599 patent. *See id.*, ¶ 30 (acknowledging that Apotex's ANDA cannot be approved until after the '599 patent and attendant exclusivity expires). On June 12, 2012, Apotex provided Daiichi Sankyo with a notice letter concerning its ANDA, in which Apotex stated that the '703 patent has been disclaimed and has expired for failure to pay maintenance fees. *See id.*, ¶ 28. On July 3, 2012, Daiichi Sankyo, through counsel, confirmed to Apotex that the '703 patent had been disclaimed and Daiichi Sankyo "cannot, and does not intend to," sue Apotex for infringement of the '703 patent. *See Ginnings Decl.*, Exh. 3.

¹ Under the Hatch-Waxman Act, an NDA holder who completes pediatric studies is entitled to an additional six months of marketing exclusivity. *See* 21 U.S.C. § 355a. Thus, while the '599 patent expires in April 2016, Mylan's ANDA cannot be granted final approval until October 2016.

D. Apotex's Declaratory Judgment Complaint

Despite these assurances, and the knowledge that the '703 patent has been disclaimed, Apotex filed suit for a "declaration of non-infringement of" the '703 patent in its November 20, 2012 complaint and its February 12, 2013 amended complaint. Am. Compl. (D.I. 10), ¶ 1.

In its amended complaint, Apotex averred the following in support of its position that the '703 patent cannot be infringed:

- "[T]he term of every claim of the '703 patent was disclaimed." *Id.*, ¶ 18.
- "Because the '703 patent has expired for failure to pay maintenance fees and every claim was disclaimed, the manufacture, marketing, use, and and/or importation of [Apotex's generic product] will not ... infringe ... the '703 patent." *Id.*, ¶ 37.

As to Apotex's entry to the market, its complaint states that:

- "[T]he earliest possible date that Apotex can obtain final [approval of its ANDA] is upon expiration of the '599 patent and any applicable pediatric exclusivity." *Id.*, ¶ 30.
- "Mylan retains a 180-day first generic applicant exclusivity." *Id.*, ¶ 33.
- "Mylan's exclusivity period ... will block final FDA marketing approval of Apotex's ANDA even after the expiration of the '599 patent." *Id.*, ¶ 40.

Thus, Apotex is blocked from the market by another patent, the '599 patent; indeed, Apotex does not seek to market its generic product until after the "expiration of the '599 patent and any applicable pediatric exclusivity." *See id.*, ¶ 30. The '599 patent, together with its pediatric exclusivity period will not expire until October 25, 2016. And, Apotex is blocked by the statutory exclusivity of non-party Mylan. Apotex seeks to destroy this statutory exclusivity by asking this Court to issue a metaphysical declaratory judgment declaring that Apotex does not infringe a patent that does not exist.

ARGUMENT

This Court should dismiss Apotex's complaint for lack of subject matter jurisdiction because there is no case or controversy here. Apotex admits that the '703 patent has been

disclaimed which means it does not exist (and can never be asserted against Apotex). Under basic patent law principles this leaves no controversy on infringement for the Court to decide. Apotex admits that what it really seeks is to destroy Mylan's statutory exclusivity which blocks Apotex from the market. But, the Hatch-Waxman case law is clear that "exclusion from the market because of [another generic company's]... entitlement to this statutory exclusionary period does not present a justiciable Article III controversy." *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1362 (Fed. Cir. 2008). Finally, Apotex admits that its own acquiescence to the '599 patent blocks it from the market, thus the one rare scenario where a case or controversy may exist (if the non-asserted patent was the only barrier to market) does not apply.

Regardless, additional reasons exist for this Court to exercise its discretion and decline to hear Apotex's complaint. Apotex's complaint is hypothetical because its ANDA has not yet and may never obtain approval from the FDA – and, even ignoring all of the other jurisdictional deficiencies, this alone prevents the "trigger" of Mylan's exclusivity period that Apotex seeks.

I. Legal Standard for Motions to Dismiss

A motion to dismiss under Fed. R. of Civ. P. 12(b)(1) challenges the court's subject matter jurisdiction. Apotex bears the burden of proof on subject matter jurisdiction. *United Phosphorus, Ltd. v. Angus Chem. Co.*, 322 F.3d 942, 946 (7th Cir. 2003). In ruling on a motion to dismiss, the court must accept all well-pleaded facts in the complaint. *Sapperstein v. Hager*, 188 F.3d 852, 855 (7th Cir. 1999). However, the court may consider materials submitted by the movant without converting the motion to one for summary judgment. *See id.*

II. Apotex's Complaint Should Be Dismissed for Lack of Subject Matter Jurisdiction

A case or controversy exists under the Declaratory Judgment Act when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having

adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citation omitted). The dispute must be “definite and concrete, touching the legal relations of parties having adverse legal interests;” also, it must be “real and substantial” and “admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.” *Id.* (citation omitted).

A court also has discretion to decline to hear a declaratory judgment action. A court can decline to issue a declaratory judgment that would not “serve a useful purpose,” *Int’l Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1218 (7th Cir. 1980), or would not “terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding.” *Tempco Elec. Heater Corp. v. Omega Eng’g, Inc.*, 819 F.2d 746, 749 (7th Cir. 1987) (internal quotations and citations omitted).

A. There Is No Case or Controversy Between Apotex and Daiichi Sankyo Because the ’703 Patent Has Been Disclaimed.

Apotex’s complaint should be dismissed because there is no justiciable controversy between Daiichi Sankyo and Apotex on the ’703 patent. Apotex acknowledges in its amended complaint that the ’703 patent has been statutorily disclaimed. Am. Compl. (D.I. 10), ¶ 18.² As such, the patent ceases to exist. *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (the effect of disclaimer as that of canceling the claims from the patent” as if they had “never existed.”);

² While Apotex also avers that the ’703 patent has “expired for failure to pay maintenance fees,” Am. Compl. (D.I. 10), ¶ 19, and the U.S. Patent Office Maintenance Fee Docket indicates an expiration for failure to pay a maintenance fee, the ’703 patent was disclaimed long before the date on which the maintenance fee was due. It thus ceased to exist and could not subsequently expire for failure to pay maintenance fees. Regardless, either a disclaimer of the ’703 patent *or* an expiration for failure to pay maintenance fees would divest Daiichi Sankyo of the right to assert the ’703 patent against anyone, and result in no justiciable controversy between Daiichi Sankyo and Apotex on the ’703 patent.

W.L. Gore & Associates, Inc. v. Oak Materials Group, Inc., 424 F. Supp. 700, 702 (D. Del. 1976) (disclaimer is “the same as dedication of the patent to the public or abandonment.”). Daiichi Sankyo cannot assert the ’703 patent against Apotex or anyone else. *See, e.g., Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) (noting that disclaimer “effectively eliminate[s] ... claims from the original patent”). When a patent has been disclaimed, there can be no subject matter jurisdiction. *See, e.g., 3V v. CIBA Specialty Chemicals Corp.*, 587 F. Supp.2d 641, 645-46 (D. Del. 2008) (no case or controversy over disclaimed patent, despite litigant’s wish to establish facts for future cases); *W.L. Gore & Associates*, 424 F. Supp. at 702.

B. Even Under the Hatch-Waxman Act, There Is No Case or Controversy Between Apotex and Daiichi Sankyo.

Apotex cannot—and does not—argue that, as a general matter, a disclaimed patent can be infringed; rather, Apotex appears to be contending that this case is somehow unique because it arises under the Hatch-Waxman Act. Nothing in the Hatch-Waxman Act changes the fact that there is no case or controversy here.

Apotex says that it seeks “a declaratory judgment of noninfringement” in order to “trigger ... Mylan’s exclusivity period” and “allow it to bring its ANDA product to market upon the expiration of the ’599 patent.” Am. Compl. (D.I. 10), ¶ 40. Apotex also alleges that Apotex is “injured by Daiichi [Sankyo]’s actions of requesting the FDA to list the ’703 patent in the FDA Orange Book and continuing said listing in the FDA Orange Book.” *Id.*, ¶ 39. These allegations do not give rise to a case or controversy.

1. The Federal Circuit Has Affirmed Dismissals for Lack of Subject Matter Jurisdiction Under Nearly Identical Facts.

Previous attempts to manufacture a case or controversy in order to destroy another company’s generic exclusivity, like this one, have been dismissed as lacking subject matter

jurisdiction and those dismissals affirmed by the Federal Circuit. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008); *Merck & Co. v. Apotex, Inc.*, 2007 WL 4082616 (D.N.J. 2007), *aff'd* 292 Fed. Appx. 38 (Fed. Cir. 2008).

a. **Janssen: Exclusion from the Market By Another's Statutory Exclusionary Period Does Not Present a Justiciable Article III Controversy.**

In *Janssen*, Teva Pharmaceuticals USA, Inc. ("Teva") was the first to file a Paragraph IV Certification on three Orange Book listed patents for Respidal® and was thus (like Mylan here) entitled to 180 days of generic exclusivity. 540 F.3d at 1358. Apotex later also made Paragraph IV Certifications against the three patents. *Id.* Janssen sued Apotex for infringement of only one of the three patents (the "'663 patent"). *Id.* Apotex stipulated to the infringement and validity of the '663 patent and agreed not to launch its product until the '663 patent expired (just as here it agrees it will not launch its product until the '599 patent expires). *See id.* Apotex counterclaimed for declarations of noninfringement of the two unasserted patents. *Id.* Janssen granted Apotex covenants not to sue on those patents and moved to dismiss. *See id.* at 1358-59.

Apotex argued (just as it argues here) that a case or controversy existed because the Teva's statutory exclusivity blocked Apotex from entering the market. *See id.* at 1359. The court explained that the harm of which Apotex was complaining was due to the provisions of the Hatch-Waxman Act, not Janssen's actions. Specifically, the court said:

[T]he harm to Apotex that has continuously existed is its exclusion from selling its alleged noninfringing product *during* Teva's statutorily entitled 180-day exclusivity period. Apotex is being excluded from the market by Teva's 180-day exclusivity period – ***a period which Teva is entitled to under the Hatch-Waxman Act.***"

Id. at 1361 (emphasis added). The Federal Circuit concluded there was no case or controversy:

Apotex's exclusion from the market because of Teva's entitlement to this statutory exclusionary period does not present a justiciable Article III controversy.

Id. at 1362.

Janssen is indistinguishable and controlling. First, just as in *Janssen*, Apotex has no risk of being found to infringe the '703 patent. In *Janssen*, the patentee covenanted not to sue on the patents for which Apotex sought declaratory judgment. Here, Daiichi Sankyo disclaimed the '703 patent and it no longer exists. *See* Am. Compl. (D.I. 10), ¶¶18, 19 and Exhs. D, E. Second, in *Janssen* and here, Apotex opted not to challenge other, blocking patents and wait to launch its generic product until after those blocking patents expired. Just as Apotex stipulated to the validity of the '663 patent in *Janssen*, here it has agreed to respect the validity of the '599 patent; it has filed a Paragraph III Certification against that patent and, therefore, has agreed to stay off the market until the “expiration of the '599 patent and any applicable pediatric exclusivity.” *Id.*, ¶ 30. Under *Janssen*, Apotex is not entitled to a declaratory judgment merely to trigger Mylan’s potential exclusivity—“exclusion from the market [because of another’s] entitlement to this statutory exclusionary period does not present a justiciable Article III controversy.” *Id.* at 1362.

b. Merck: No Subject Matter Jurisdiction When Patent Had Been Disclaimed

As in *Janssen*, the Federal Circuit affirmed the district court’s conclusion that a case or controversy does not exist under nearly identical facts to this case in *Merck & Co., Inc. v. Apotex, Inc.*, 2007 WL 4082616 (D.N.J. 2007), *aff’d* 292 Fed. Appx. 38 (Fed. Cir. 2008). There, Hi-Tech Pharmacal, Co., Inc. (“Hi-Tech”) was the first to file a Paragraph IV Certification against the three Orange Book listed patents for Cosopt®. *Id.* at *3. Merck asserted one of the patents (the “’413 patent”) against Hi-Tech and statutorily disclaimed the other two. *Id.* at *2.

Merck prevailed at trial against Hi-Tech, but while the district court’s decision was on appeal, Apotex also made a Paragraph IV Certification against all three listed patents. *Id.* Merck asserted the '413 patent against Apotex, and Apotex counterclaimed for a declaration of non-

infringement of the disclaimed patents. *Id.* at *3. Apotex agreed to be bound by the decision in Merck's case against Hi-Tech. *Id.* The Federal Circuit affirmed Merck's district court victory against Hi-Tech, and the district court entered judgment against Apotex on the '413 patent. *Id.*

Merck moved to dismiss Apotex's counterclaims concerning the two disclaimed patents for lack of subject matter jurisdiction. *Id.* The district court held that no case or controversy existed, stating that "because Merck has formally disclaimed the ... patents, and can no longer enforce any claims as to these patents, there is no justiciable case or controversy to support jurisdiction in an action for a declaratory judgment here." *Id.* at 5 (internal citation omitted). The Federal Circuit affirmed the district court's ruling. 292 Fed. Appx. 38.

Merck is just as indistinguishable as *Janssen*. Apotex is the second Paragraph IV filer here, just as it was in *Merck*. Also, just as Merck disclaimed the two patents for which Apotex sought a declaratory judgment in *Merck*, here Daiichi Sankyo has disclaimed the '703 patent. There is no case or controversy here under this controlling law.

2. The Facts Here Match *Janssen* and *Merck*, Not the One Rare Scenario Where a Case or Controversy May Exist.

There is a rare exception to the above settled law; a case or controversy may exist in the Hatch-Waxman context if "[a] favorable judgment in [the declaratory judgment action] would clear the path to FDA approval that [the NDA holder's] actions would otherwise deny" the ANDA filer. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1293 (Fed. Cir. 2008); *see also Dey Pharma LP v. Sunovion Pharms. Inc.*, 677 F.3d 1158, 1163-64 (Fed. Cir. 2012) (analogizing to *Caraco*). That is not the case here; another patent blocks Apotex from approval.

In *Caraco*, second ANDA filer Caraco made a Paragraph IV Certification against the two Orange Book listed patents for Lexapro®. *Id.* at 1288. Forest sued Caraco for infringement of

one patent but not the other. *Id.* Caraco then filed a declaratory judgment complaint for non-infringement of the unasserted patent. *Id.* Forest moved to dismiss, but the district court concluded that a case or controversy existed. *Id.* at 1288-90. The Federal Circuit affirmed because both Orange Book listed patents were being challenged: “[i]f Caraco obtains a favorable judgment that the drug described in its ANDA does not infringe [the asserted patent], then it will only need a judgment of invalidity or noninfringement on [the unasserted patent] in order to activate [the] exclusivity period and obtain FDA approval.” *Id.*; *see also Dey*, 677 F.3d at 1164 (“eliminating one barrier is sufficient for declaratory jurisdiction” only if “litigation is also pending that could eliminate the other barriers.”).

Unlike in *Janssen* or here, Caraco challenged *both* Orange Book patents—the asserted patent (in Forest’s suit) and the unasserted patent (in its declaratory judgment suit). *See also Dey*, 677 F.3d at 1163-64 (noting that Dey had challenged all Orange Book listed patents). Here, *Apotex has not challenged the ’599 patent* and has affirmatively acquiesced to this barrier to approval of its ANDA. Similarly, in *Janssen*, the Federal Circuit explicitly distinguished *Caraco* because Apotex had stipulated to the validity of the ’663 patent and could not obtain FDA approval until it expired. *Janssen*, 540 F.3d at 1361; *see also Dey*, 677 F.3d at 1163 (analogizing to *Caraco* because Dey had not stipulated to validity of any patent). Thus, the facts here are the same as in *Janssen*, whereas the facts of *Caraco* (and *Dey*) are distinguishable.

C. The Orange Book Listing Does Not Establish a Case or Controversy Between Apotex and Daiichi Sankyo.

Apotex also alleges that a controversy exists here merely because the ’703 patent is listed in the Orange Book. Am. Compl. (D.I. 10), ¶ 39. If the mere listing of a patent in the Orange Book results in justiciable controversy between an NDA holder and a Paragraph IV filer, a

justiciable controversy would have existed in *Janssen*, 540 F.3d at 1357 (noting Orange Book listing of all four patents), but it did not.

Regardless, the Orange Book listing for the Benicar® product does not create a case or controversy. Daiichi Sankyo was required to identify to the FDA every patent potentially covering a generic copy of the Benicar® product. *See* 21 U.S.C. § 355(b)(1). And, after disclaimer, the '703 patent remained listed in the Orange Book by operation of law, not Daiichi Sankyo's actions. Daiichi Sankyo asked the FDA to remove the '703 patent from the Orange Book in 2006. *See* Ginnings Decl., Exh. 1. The Orange Book notes this delisting request. *See id.*, Exh. 2. The FDA, however, did not delist the patent because Mylan had already filed a Paragraph IV Certification against it, and the FDA cannot delist patents once a Paragraph IV Certification is filed. *See, e.g., Teva Pharms USA, Inc. v. Sebelius*, 595 F.3d 1303, 1315-18 (D.C. Cir. 2010); *see also Apotex, Inc. v. Sebelius*, 700 F. Supp. 2d 138, 139-41 (D.D.C. 2010) (concluding that expiration of a listed patent does not cause forfeiture of generic exclusivity).

Apotex's inability to promptly launch its generic drug product because of Mylan's 180-day exclusivity period under the Hatch-Waxman Act is not a cognizable Article III controversy, but rather is a result envisioned by the Act. *Janssen*, 540 F.3d at 1361.

D. The Court Should Decline to Exercise its Declaratory Judgment Jurisdiction Because This Action is Premature.

Additionally, this Court should decline to exercise its jurisdiction because Apotex's complaint is premature and hypothetical in that its ANDA has not obtained tentative approval. Thus, the declaration Apotex seeks would not serve any useful purpose or afford any real relief.

Apotex's complaint states that its injury is "being prohibited from selling its product" by Mylan's "180-day first generic applicant exclusivity" and that "Apotex's injury can be redressed by the requested relief: a declaratory judgment of noninfringement would trigger first applicant

Mylan's exclusivity period" Am. Compl. (D.I. 10), ¶¶ 33, 40. However, Apotex does not appear to have—and may never obtain—"tentative approval" from the FDA, which is required to trigger the first Paragraph IV filer's exclusivity. The statute explains that exclusivity is only triggered when declaratory judgment action brought by "the first applicant or any other applicant (which other applicant has received tentative approval)." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Apotex is an "other applicant" because Mylan is the "first applicant." *See* Am. Compl. (D.I. 10), ¶ 31. Thus, unless and until Apotex obtains tentative approval, judgment here cannot trigger Mylan's exclusivity.³ Apotex's assertion that "a declaratory judgment of noninfringement would trigger ... Mylan's exclusivity period" is legally wrong and its complaint hypothetical.

³ Apotex's lack of tentative approval also prevents it from suing the FDA to compel any action with respect to Mylan's ANDA. *See Mylan Pharms. Inc. v. U.S. Food and Drug Admin.*, 789 F. Supp. 2d 1, 9 (D.D.C. 2011).

CONCLUSION

For the reasons stated above, this Court should dismiss Apotex's amended complaint.

Respectfully submitted,

Dated: April 9, 2013

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***Attorneys for Defendants, Daiichi Sankyo,
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CERTIFICATE OF SERVICE

The undersigned attorney, upon oath, hereby certifies that he served a copy of the foregoing Memorandum in Support of Defendants' Motion to Dismiss Plaintiff's Amended Complaint upon the parties by causing a true and correct copy thereof to be electronically filed and delivered using the Court's ECF system on the 9th day of April, 2013.

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Dated: April 9, 2013

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